

REMARKS

Claims 14, 17-19, 21-24, 27, 28, 31, 34-37 and 39-41 are pending in the present application. In view of the following remarks, reconsideration and allowance of the claims are respectfully requested.

I. Double Patenting

The Patent Office provisionally rejects 14, 17-19, 21-24, 27, 28, 31, 34-37 and 39-41 under the judicially created doctrine of nonstatutory obviousness-type double patenting over co-pending U.S. Application No. 12/021,546. Because the cited co-pending application has not issued, filing a Terminal Disclaimer to obviate a provisional double patenting rejection is premature. See MPEP §706.02(k).

Accordingly, Applicants respectfully request abeyance of the double patenting rejection.

II. Rejection Under 35 U.S.C. §103

The Patent Office rejects claims 14, 19, 28, 31 and 38 under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 7,056,591 ("Pacetti"). This rejection is respectfully traversed.

At least because Pacetti does not disclose, nor does Pacetti provide any reason or rationale for one of ordinary skill in the art to have modified its stent coating to have incorporated a delivery vehicle selected from the group consisting of microcapsules, microspheres, barriers, liposomes, osmotic pumps, fibers, filaments, gels, foams and films, Pacetti would not have rendered obvious each and every feature of claims 14 and 28.

Pacetti is "directed to coatings for implantable medical devices, such as drug eluting vascular stents" (Pacetti, col. 1, lines 9-10). A person of ordinary skill in the art would have understood an "implantable medical device" to be defined as a medical device that is partly or totally inserted into the human body or a natural orifice and is expected to stay there for 30 days or more, or is used to replace an epithelial surface or the surface of the eye and is expected to stay in use for 30 days or more. Surgical or medical procedures are used to insert or apply implantable medical devices and surgical or medical procedures must be used to remove them (see e.g., ISO 13485 2003 Plain English Definitions, Quality Management Standard for Medical Devices). That same person of ordinary skill would have understood that microcapsules, microspheres, barriers, liposomes, osmotic pumps, fibers, filaments, gels, foams and films, as recited in claims 14 and 28, are not implantable medical devices in the art.

Nevertheless, consistent with the above definition of 'implantable medical device', Pacetti discloses "[e]xamples of such implantable devices include self-expandable stents, balloon-expandable stents, stent-grafts, grafts (e.g. aortic grafts) (sic). [Pacetti's] coating can also be used with artificial heart valves, cerebrospinal fluid shunts, coronary shunts, pacemaker electrodes and endocardial leads" (Pacetti, col. 8, lines 44-45 and 49-55).

However, nowhere does Pacetti disclose a delivery vehicle comprising Pemirolast wherein the delivery vehicle is selected from the group consisting of microcapsules, microspheres, barriers, liposomes, osmotic pumps, fibers, filaments, gels, foams and films, as recited in claims 14 and 28, and nor does the

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Office Action provide a citation to any portion of Pacetti in support of such an allegation. The Office Action merely states that:

"Pacetti et al discloses a polymer coating for a medical device (see Abstract). Polymers used for the coaing (sic) are listed at col. 7, lines 65-67; col. 3, lines 1-32...Therefore those of ordinary skill would have therefore found it well within their skill to coat a medical device with the claimed polymers used to deliver Permiolast, with a reasonable expectation of anti-allergic results. The instant invention would therefore been obvious to the of (sic) ordinary skill in the art at the time of invention given the teachings of US'591 to form a polymer coating comprising Pemiolast...the drug delivery coating [of Pacetti] is used for...local, non-systemic delivery. As for the delivery vehicle itself, osmotic pumps clearly fall within this category as well."

(Office Action, page 4).

As shown above, the Examiner's own reasoning demonstrates that Pacetti does not contain any teaching or suggestion that would have directed one of ordinary skill in the art to have modified Pacetti's coating for a stent and replaced the stent (or implantable medical device) with any of the drug delivery vehicles specified in claims 14 and 28 (e.g., an osmotic pump). Pacetti is silent as to microcapsules, microspheres, barriers, liposomes, osmotic pumps, fibers, filaments, gels, foams and films. Apart from acknowledging that osmotic pumps provide local, non-systemic delivery, the rationale provided by the Examiner for modifying Pacetti is nothing more than a mere conclusory statement alleging that drug delivery vehicles (regardless of whether it is a stent or an osmotic pump) are interchangeable to the extent that one of ordinary skill in the art would have

replaced the stent of Pacetti with a delivery vehicle as specified in the instant claims. Such an assertion amounts to nothing more than picking and choosing of elements based solely on hindsight and the disclosure of the instant claims, without any logical reason for the picking and/or choosing. See *In re Wesslau*, 147 USPQ 391, 393 (CCPA 1965).

At most, even if one were led to replace the stent of Pacetti, the logical choice would have been to select from a variety of implantable medical devices, as they are specifically disclosed as being used in combination with the coating of Pacetti (Pacetti, col. 8, lines 44-45 and 49-55). Furthermore, significant differences exist between stents and, for example, osmotic pumps, which act against any assertion to interchange the two in the manner alleged by the Patent Office.

Drug-eluting stents are generally diffusion controlled systems, driven by moving molecules from a solution of high concentration to low concentration. The active drug is released by passing through pores or polymer chains, which control the release rate. Drug delivery systems in the context of stenting are a culmination of factors involving stent design and manufacture, coating technology and drug pharmacology. On the other hand, osmotically-controlled devices are water penetration-controlled systems, designed to have a semi-permeable membrane that allows water to move in, but prevents salt and drug molecules from moving out. Here, a rigid, water-permeable membrane controls the delivery rate.

Accordingly, in further view of at least these significant dissimilarities, one of ordinary skill in the art would have had no reason or rationale to have understood that Pacetti's coating, specifically designed for stents and implantable devices can or should be compatible in conjunction with microcapsules, microspheres, barriers, liposomes, osmotic pumps, fibers, filaments, gels, foams and films, without at least the improper hindsight benefit of Applicants' specification.

Any assertion that one of ordinary skill in the art would have modified Pacetti to have obtained each and every feature of the instant claims, without any reason or rationale in Pacetti to have made such a modification, and further because Pacetti is silent as to microcapsules, microspheres, barriers, liposomes, osmotic pumps, fibers, filaments, gels, foams and films, is improper hindsight reasoning based solely upon Applicants' disclosure and does not constitute a showing of *prima facie* obviousness.

Based on the above, Pacetti would not have rendered claims 14 and 28 obvious. The remaining claims variously depend from claims 14 and 28 and are patentable for at least the reasons that claims 14 and 28 are patentable, as well as for the additional features recited therein.

Accordingly, reconsideration and allowance of the claims are respectfully requested.

III. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt notification of allowance are respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 50-2478 (14758).

Should the Examiner believe that anything further would be desirable in order to place this application in condition for allowance, the Examiner is invited to contact the undersigned representative at the telephone number set forth below.

Respectfully submitted,

Date: July 11, 2011

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